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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,588	MAJID ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *5-10 and 14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,11 and 12* is/are rejected.

7)☒ Claim(s) *3 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-24 are pending.

Election/Restrictions

2. In response to the restriction requirement, Applicant has elected with traverse to prosecute the invention of Group I, claims 1-4, 11-13, drawn to a compound of formula I, and the composition thereof. Claims of Groups II-IV are withdrawn from further consideration as being drawn to the non-elected invention.

Applicants argue that the classes of the restricted groups have not been provided. In response, the restriction requirement with the class and subclass is restated as below.

I. Claims 1-4 and 11-13, drawn to a compound of formula I, and the composition thereof, classified in class 546, subclass 82.

II. Claims 6-10, drawn to multiple methods of use with the compound of claim 1, classified in class 514, subclass 293.

III. Claims 14-24, drawn to multiple method of use with a compound of formula I, class 514, subclass various dependent on the species elected.

IV. Claim 5, drawn to a composition comprising multiple active ingredients, class and subclass various dependent on the species active ingredients.

Applicants submit that the search of all the claims 1-24 should not impose any undue burden on the examiner.

On the contrary, a reference anticipating the compound of Group I would not necessarily render obvious the method of Group II. For example, the compound of Group I is anticipated or rendered obvious by the inflammatory compound of Tully (GB 2185255), but not the method of Group II. The search is therefore not co-extensive and is therefore burdensome.

Furthermore, inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different processes, such as for the treatment of atherosclerosis, Alzheimer's disease, diabetes etc .

The Group II process of use is for treating a disease condition associated with the increased NIK activity with the inventive compound, whereas the Group III process of use is for treating a disease condition associated with inflammation with the compound of formula I, which has a scope different from the compound of Group II. A reference anticipating the compound of Group II would not necessarily render obvious the method of Group III.

The patentability of Group IV invention depends on the type and amount of the multiple active ingredients, their interaction, co-action, e.g. synergism etc., which is patentably distinct from the Group I compositions containing only a single active ingredient.

Since the search required for Group I is not required for Group II or III or IV, restriction for examination purposes as indicated is proper.

Claim Rejections - 35 USC § 112

3. The amendment has obviated the rejection for Claims 1-2, 5, 11, 12 under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102(b)

4. The rejection under 35 U.S.C. 102(b) as being anticipated by Tully (GB 2185255, PTO-1449) is withdrawn in view of the amendment excluding the compounds of Tully from the claims.

Claim Rejections - 35 USC § 102(e)

5. The rejection under 35 U.S.C. 102(e) as being anticipated by Flohr (6841556, with a priority of provisional application 60/423954, filed on 11-5-2002, which is before the instant 7-3-2003) is withdrawn in view of the amendment excluding the compounds of Flohr from the claims.

Double Patenting

6. The timely filed terminal disclaimer has obviated the obviousness-type double patenting rejection over claims 1-3, 11-12 of U.S. Patent No. 6841556.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 11, 12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 11, the new subgenus of compounds in the proviso is not described in the specification. The rejection is applicable to claims 2, 12, which are dependent on claims 1, 2 respectively.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tully (GB 2185255).

Tully generically discloses an anti-inflammatory pyrazoloisoquinoline compound (page 1). Specific compounds are described on page 6, Table 1, Examples 1, 5, 7.

Tully's example 1 has a 3-methyl as R3 (corresponding to the instant A), whereas the instant 3-ethyl-5-phenyl-1H-pyrazolo[4,3-c]isoquinoline (page 9, 4th compound) has a 3-ethyl. The instant is therefore the next adjacent homolog of Tully's example 1.

Tully further teaches that methyl and ethyl are optional choices (page 1, line 24).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the methyl with the homologous, optional ethyl as taught by Tully to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-inflammatory compound, since Tully had clearly teaches that any species within the small disclosed genus would be useful for treatment of inflammation.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flohr (6841556).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Flohr generically discloses a NIK inhibiting pyrazoloisoquinoline compound (columns 23-4, claim 1). Specific compounds are claimed (column 24, claim 3).

Flohr's 3-methyl-5-pyridine-1H-pyrazolo[4,3-c]isoquinoline has a 3-methyl (column 25, lines 2-3), whereas the instant 3-ethyl-5-pyridine-1H-pyrazolo[4,3-c]isoquinoline (page 9, 5th and 6th compound) has a 3-ethyl. The instant is the next adjacent homolog of Tully's example 1.

Flohr further teaches that methyl and ethyl are optional choices (column 23, claim 1, line 16, definition of A).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the prior art methyl with the homologous, optional ethyl to arrive at the instant invention with the reasonable expectation of obtaining an additional NIK-inhibiting compound, since Flohr had clearly teaches that any species within the disclosed genus would be useful for the inhibition of NIK.

Allowable Subject Matter

9. Claim 3, 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The instant compounds having a 3-trifluoromethyl, 5-trifluoromethyl-phenyl, 1-methyl, 1-benzyl, 5-methoxymethyl, 7-methoxylcarbonyl, or 6, 7 or 8-dimethylamino substituents, and the composition thereof, are not taught or suggested by Tully (GB 2185255, PTO-1449) or Flohr (6541556).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625